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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,673	08/19/2003	Suong-Hyu Hyon	1736-000001/REC	5763

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EXAMINER	
BERMAN, SUSAN W	

ART UNIT	PAPER NUMBER
1711	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,673	HYON ET AL.	
	Examiner	Art Unit	
	Susan W. Berman	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/05,01/06,03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 12-15,17,19,20,22-24,27,29,31-34,36-41,43,44,46,48-53,56-61,63,64,66,68-70,73-75,77-80,83-85,87,88,104-148 and 226.

Continuation of Disposition of Claims: Claims rejected are 12-15,17,19,20,22-24,27,29,31-34,36-41,43,44,46,48-53,56-61,63,64,66,68-70,73-75,77-80,83-85,87,88,104-148 and 226.

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Response to Remarks

Applicant's arguments filed 10/18/2005 have been fully considered but they are not persuasive for the following reasons.

The issue of the objection to the application under 1.172(a) is discussed below.

With respect to element equivalence as set forth in Appendix B: Applicant asserts that the instantly claimed "heated at a temperature from its melting point minus 50^0C to its melting point plus 80^0C" is equivalent to the recitation "thermally treated according to the method selected from the groups consisting of annealing and remelting" in the claims of Shen et al '900. This argument is not persuasive. The instantly disclosed method step is one of compression-deformation of a previously irradiated UHMWPE at a temperature from its melting point minus 50^0C to its melting point plus 80^0C. The annealing step claimed by Shen et al is defined as heating below the melting temperature of the crosslinked polymer. The remelting step claimed by Shen et al is defined as heating above the melting temperature of the crosslinked polymer. Shen et al do not disclose compression-deformation during either heating step. It is agreed that the "remelting" step taught by Shen is so-called because it refers to a melting step after a prior melting step that takes place when UHMWPE resin powder is heated and consolidated to form the preform on which irradiation and remelting is carried out. Thus, the heating during compression-deformation disclosed by applicant is equivalent to the heating and consolidation step taught by Shen et al.

Reissue Applications

This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172*(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b). Applicant's statement has the party who is signing also stating that he is "empowered to sign this certificate". The language the party is "empowered to sign this certificate" instead of "the party is empowered to act on behalf of the assignee" is acceptable; however, **the same person who is making the statement also signing the consent form is not acceptable.**

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action. A paper must be filed to designate Yoko Gen, C.E.O. of BMG Incorporated, as a person empowered to sign on behalf of the assignee and be signed by someone, such as the inventor or attorney, other than Yoko Gen. The papers currently filed are unacceptable because Yoko Gen is empowering himself to consent to the reissue application. It is suggested that applicant's attorney sign the statement establishing that BMG Incorporated is the Assignee and authorizing C.E.O. Yoko Gen to sign in behalf of BMG Incorporated. Then the paper "Assignee Consent under 37 C.F.R. 1.172" to filing of a reissue application can be signed by Yoko Gen as C.E.O. of BMG Incorporated.

Response to Amendments

The copy submitted 10/18/2005 of the new claims 12-148 submitted 08/19/2003, wherein the new claims are underlined in their entirety, has been entered.

The rejections of claims under 35 U.S.C. 112, first and second paragraphs, are withdrawn in response to the amendments, with the one exception set forth below.

Claim Objections

Claim 79 is objected to because of the following informalities: The first occurrence of "melting" should read "melting point". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-15, 38-41, 43, 44, 46, 48-52, 53, 56, 57, 58-61, 63, 64, 70, 7-75, 77-80, 83 and 84, 85, 87, 88, 104-113 and 146 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe the following subject matter employed in the claims: The recitation of "medical implant" in claims 12 and 146 instead of "molded article for artificial joints", "artificial joints" or "socket for artificial joints" broadens the scope of subject matter originally described in the specification since medical implants other than artificial joints are known in the art. With respect to claim 104, the examiner has not found any disclosure of irradiating a raw article "comprising" UHMWPE. The specification discloses

irradiating a "raw UHMWPE" molded article" (see column 2, line 49, and column 3, lines 21-25). The recitation "raw article comprising UHMWPE" broadens the scope of subject matter originally described in the specification since it encompasses mixtures or blends of UHMWPE with other materials not described in the specification as originally filed.

With respect to claims 38-41, 43, 44, 46, 48-52, 53, 56, 57, 58-61, 63, 64, 70, 7-75, 77-80, 83 and 84, which recite irradiating UHMWPE "below its melting point", applicant discloses that the temperature during irradiation may be room temperature or a higher temperature no less than the crystal transition point (80^0C). See column 3, lines 43-46 and the examples.

With respect to claims 85, 87 and 88, which recite irradiating UMWPE "in a solid state", applicant discloses that the temperature during irradiation may be room temperature or a higher temperature no less than the crystal transition point (80^0C). See column 3, lines 43-46 and the examples.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-15, 17, 19, 20, 22-24, 26, 27, 29, 31-34, 36-41, 43, 44, 46, 48-53, 56, 57-61, 63, 64, 66, 68-70, 73, 74, 75, 77-80, 83-85, 87, 88, and 104-148 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12, 17, 27, 46, 53, 58, 66, 70, 85, 104, 112, 114, 120, 122, 128, 130, 137, 139 130, 139 and 146 do not clearly set forth that the UHMWPE is slightly crosslinked by low dose irradiation, the irradiated UHMWPE is heated to its compression-deformable temperature by heating at a temperature from its melting point minus 50^0C to its melting point plus 80^0C, compression deformed at its compression-deformable

temperature and cooled while keeping the deformed state, as disclosed (column 2, lines 47-55). Claim 38 does not clearly set forth that the UHMWPE is slightly crosslinked by low dose irradiation and then the irradiated UHMWPE is heated to the irradiated UHMWPEs compression-deformable temperature by heating at a temperature from its melting point minus 50^0C to its melting point plus 80^0C.

Claims 22, 33 do not have antecedent basis in claims 17, 27 for "during processing into an implant" since processing into an implant is not mentioned in claims 17, 27. It is suggested that the claims be rewritten to recite that "said...polyethylene is further processed by cutting into an implant".

Claim 29 does not have antecedent basis in claim 27 because claim 27 recites an artificial joint, not a "medical implant". Claim 50 does not have antecedent basis in claim 46 for the recitation "is melted at a temperature" in line 2 because Claim 46 recites "heating...at a temperature", not "melting".

In claims 46 and 66, does applicant intend to claim cutting the UHMWPE article while heated? It is believed that the specification describes cutting into an implant after cooling the crosslinked and heat treated article.

Claim 58 is indefinite because the phrase "over untreated ultrahigh molecular weight polyethylene" in the last two lines does not clearly set forth that the comparison is with the same kind of UHMWPE as the "starting ultrahigh molecular weight polyethylene" recited in line 3. The claim, as written, encompasses comparing the wear resistance of a treated UHMWPE having a significantly different molecular weight than an untreated UHMWPE.

In claims 73, 85, 122, 139, it is not clear what steps are encompassed by the term "processing". If applicant intends to distinguish the instantly claimed method from that taught by

Sun et al, it is suggested that the claims clearly recite a compression-deformation step after the irradiation and heat treatment steps set forth in the claims. The term "processing" includes steps such as packaging, cutting to remove oxidation, further annealing, etc.

Claim 124 does not clearly set forth that the "additionally comprising heating said irradiated article...20 hours" is an "isothermal crystallization" process carried out after the disclosed compression-deformation and cooling steps (see column 4, lines 4-67).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15, 17, 19, 20, 22-24, 26, 27, 29, 31-34, 36, 37-41, 43, 44, 46, 48, 49, 51, 52, 58-61, 63, 64, 66, 68-70, 73, 74, 75, 77-80, 83, 84-88, 104-107, 112-131, 137-140 and 146-148 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049). Sun et al disclose a process for providing an implant from UHMWPE. Sun et al teach that irradiation in the absence of air produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin into an UHMWPE raw material, irradiating a packaged implant of the UHMWPE raw material at a sterilizing dose of about 2.5 Mrad, and heat treating at temperatures below the melting point after irradiation to form crosslinks between free radicals produced upon irradiation. Sun et al teach shaping the treated (heated) UHMWPE by

cutting in the Examples and in column 4, lines 26-31. See column 4, lines 20-43, column 6, line 42, to column 7, line 8, methods B, C and D and the Examples.

Instant claims 12, 13, 15, 27, 29, 31-34, 36, 37, 58-61, 63, 64, 66, 68, 69, 85, 87, 88, 112-113, 120, 121, 128, 129, 137, 138, and 146-148 are considered to be anticipated wherein the articles produced by the method disclosed by Sun et al have the same properties as the articles produced by the method steps set forth in the instant claims. Sun et al teach heating the irradiated UHMWPE molded article at temperatures from 25 ^{0}C to 140 ^{0} C, thus including temperatures from the melting point minus 50^{0}C to the melting point plus 80^{0}C and temperatures from 100^{0}C to 140^{0}C as instantly claimed (see column 7, lines 3-8). Sun et al disclose 2.5 Mrad, which is within the range 1 to 5 MR set forth in the instant claims. With respect to claims 14, 50, 53, 70, 79, 107, 117 and 125, Sun et al disclose heating at temperatures up to 140^{0}C, thus teaching articles heated from temperatures from "said melting point to 140^{0}C. With respect to claims 128, 129 and 146-148, the claims do not set forth whether the "processing" step is before or after irradiation and thermal treatment. Thus, the articles produced by the method disclosed by Sun et al would be expected to have the same properties as the articles produced by the method steps set forth in the instant claims. With respect to claims setting forth the wear factor of "less than about" 9.6 x 10^{-7}, this property is considered to be an inherent property of the molded articles disclosed by Sun et al , in the absence of evidence to the contrary, because the method steps taught by Sun et al correspond to those set forth in the instant claims.

Instant claims 38-41, 43, 46, 48, 49, 51, 52, 104-106, 114-116, 122-124, 126, 127, 130, 131, 139 and 140 are considered to be anticipated for the following reasons. Step (a), requiring irradiation of UHMWPE by gamma radiation between 1 to 5 MR, corresponds to the sterilization step by irradiation disclosed by Sun et al. Since the irradiation conditions are the same, the

effects, i.e. crosslinking, would be expected to be the same. Step (b), requiring heating of the crosslinked UHMWPE at the various temperatures set forth, corresponds to the heating of the sterilization irradiated UHMWPE at temperatures from 25^0C to 140^0C for at least 4 hours taught by Sun et al.

Once a reference teaching a product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980). *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). *In re Schreiber,* 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-41, 43, 44, 46, 47, 50-53, 56, 57, 63, 64, 104-107, 111, 114-117, 122-125, 130-133, 135, 136 and 139-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. See the discussion of Sun et al above. Sun et al disclose melting and forming a polymeric resin into a raw material for forming an implant, corresponding to the instantly disclosed compression –deformation step, but do not mention the temperature ranges for compression deformation set forth in instant claims 105, 107, 115, 117, 123, 125. Sun et al disclose heat treatment corresponding to isothermal recrystallization wherein the temperature range is between about 25 ^{0}C and about 140 ^{0}C, preferably the heating is for at least 48 hours at

a temperature from 37^0 C to about 70^0 C and preferably for 144 hours at 50^0 C. Sun et al also teach that the higher the temperature the shorter the time period required for crossslinking (column 6, lines 58-61).

With respect to claims 38-41, 43, 46, 47, 49, 51, 104, 105, 114, 115, 122 and 123, which recite heating irradiated UHMWPE at a "temperature from its melting point minus 50^0C to said melting point plus 80^0C", It would have been obvious to one skilled in the art at the time of the invention to determine the optimum temperature for the heat treatment following sterilization taught by Sun et al. The reason is that Sun et al teach using the Arrhennius equation (14) to determine the temperature and time required to cause crosslinking of the free radicals generated by irradiation. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of recombining free radicals in the irradiated UHMWPE and obtaining an oxidation resistant implant, as taught by Sun et al.

With respect to claims 44, 52, 64, 106, 111, 116, 124, 130-131 and 139-140, which recite heating at a "temperature from around 100^0C to 130^0C for a period of from 1 hour to 20 hours", It would have been obvious to one skilled in the art at the time of the invention to employ a temperature around 130^0C because Sun et al teach that heating at 130^0C for 20 hours is a preferred annealing temperature and time. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of recombining free radicals in the irradiated UHMWPE and obtaining an oxidation resistant implant, as taught by Sun et al.

With respect to claims 50, 53, 56, 57, 107, 117 and 125, which recite a "temperature from said melting point to 80^0C above said melting point, It would have been obvious to one skilled in the art at the time of the invention to employ a temperature from the melting point to about 1400C, within the range from about 25^0C to about 140^0C disclosed by Sun et al and to employ a

shorter time if the packaging material could withstand the higher temperature or if the material were treated in an inert gas environment rather than being packaged in a packaging material to exclude oxygen. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of successfully reacting free radicals in the irradiated UHMWPE in a shorter time period.

With respect to claims 132-133 and 141-142, it would have been obvious to one skilled in the art to determine the rate of cooling required to obtain the desired properties since the effects of cooling rate are well known in the art with respect to polyethylene materials.

See the numerous articles and trade literature cited by applicant. One of ordinary skill in the art at the time of the invention would have been motivated to determine the optimum temperature for thermally treating and/or melting a specific UHMWPE resin and/or determine the optimum time and temperature for recrystallization and/or determine the optimum cooling rate using the process steps taught by Sun et al by a reasonable expectation of providing a polymeric material and an improved implant having increased oxidation resistance, as taught by Sun et al.

Allowable Subject Matter

Claims 108-111, 118-119, 134-136, 143-145 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Sun et al do not teach heating to a compression-deformation temperature and applying pressure during the disclosed heating step following sterilization irradiation.

Proposed Interference

Claims 12-15, 17, 19, 20, 22-24, 26, 27, 29, 31-34, 36-41, 43, 44, 46, 48-53, 56-61, 63, 64, 66, 68-70, 73-75, 77-80, 83-85, 87, 88, 104-107, 112-117, 120-133, 137-142 and 146-148 of this application have been written to encompass or overlap claims in US Patent No. 6,228,900. These claims are not patentable to the applicant for the reasons set forth herein above. because applicant does not have support within the disclosure as originally filed for the claim language employed, as set forth herein above.

An interference cannot be initiated since a prerequisite for interference under 37 CFR 1.606 is that the claims be patentable to the applicant subject to a judgment in the interference.

With respect to claims 108-111, 118-119, 134-136, 143-145, no interfering subject matter is noted. The instantly disclosed method step is one of compression-deformation of a previously irradiated UHMWPE at a temperature from its melting point minus 50^0C to its melting point plus 80^0C. The annealing step claimed by Shen et al is defined as heating below the melting temperature of the crosslinked polymer. The remelting step claimed by Shen et al is defined as heating above the melting temperature of the crosslinked polymer. Shen et al do not disclose compression-deformation during either heating step. It is agreed that the "remelting" step taught by Shen is so-called because it refers to a melting step after a prior melting step that takes place when UHMWPE resin powder is heated and consolidated to form the preform on which irradiation and remelting is carried out. Thus, the heating during compression-deformation disclosed by applicant is equivalent to the heating and consolidation step taught by Shen et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan W Berman

SB
6/11/06

Susan W Berman
Primary Examiner
Art Unit 1711